HSWMR

Hazardous Substance & Waste Management Research, Inc.

2976 Wellington Circle West
Tallahassee, Florida 32309
Phone: (850) 681-6894
Fax: (850) 906-9777
www.hswmr.com

June 4, 2010

Mr. Andrew Hackman
Senior Director of State Government Affairs
Toy Industry Association, Inc.
1115 Broadway, Suite 400
New York, NY 10010

Dear Mr. Hackman:

As a followup to our earlier submittal identifying substances proposed for removal from Ecology's Draft Reporting List, this letter report focuses on aspects of Phase 3 of the pilot phase of the rule development process for the Reporting Rule ("Rule") of Washington state's Children's Safe Product Act (CSPA). Specifically, we provide input to further refine the draft reporting list, and to propose appropriate reporting trigger levels for chemicals retained on that draft list. This letter report uses as a starting point the refined draft reporting list from our earlier submittal dated May 13, 2010 (see Table 1, attached).

Initial Recommendations

Given similar goals and target products, it seems logical that Ecology could benefit from adopting an established, effective and protective process such as the European Union guidelines under the Registration, Evaluation, and Authorization of Chemicals (REACH) system. Based upon comments from TIA members, implementing a REACH-like categorization and reporting system for chemicals of interest, particularly if other regulating bodies act similarly, would be preferable and would simplify the process considerably, helping to maintain consistency throughout the regulating and regulated communities. As an alternate approach, many of our comments herein attempt to balance Ecology's draft reporting list with a REACH-like categorization and reporting system.

Further Refine the Draft Reporting List

In addition to evaluation of appropriate reporting trigger levels, Phase 3 includes steps to be taken by Ecology to further refine the draft reporting list. At this point, we are not recommending removal of additional substances from the draft reporting list. However, with additional industry input and detailed investigation by Ecology, the information in the following sections would be reasonable for consideration during Phase 3.

Focus on CMR Substances

Other entities (e.g., European Union; EU) that have undertaken chemical classifications and prioritizations specifically for children's products have used a starting point of "CMR" substances (carcinogens, mutagens or reproductive toxins). Ecology's draft reporting list was not limited to REACH CMR chemicals; rather, it also included substances classified as endocrine disruptors, systemic irritants, and substances exhibiting persistence and bioaccumulative properties. At a minimum, the following draft reporting list chemicals likely would not appear on a consensus list of CMR substances:

- Methyl ethyl ketone
- Nonylphenol
- 4-octyl-Phenol
- Styrene monomer
- Solvent yellow
- Perfluorooctanyl sulphonic acid
- Phenol
- n-Butanol

For purposes of reporting, the Ecology list goes beyond the REACH approach. Thus, this letter report describes a mechanism for dealing with substances supplementary to the REACH listings (i.e., use of Reference Doses to prioritize and propose trigger levels).

Remove Substances that are Sequestered or not Intentionally Added

Because certain substances on the draft reporting list are inaccessible or chemically sequestered from exposure in nearly all conceivable applications (e.g., monomeric styrene and vinyl chloride, as well as acrylonitrile, due to matrix effects), a case could be made that they should be removed from the list eventually. Likewise, and consistent with Ecology's desire to limit reporting requirements to chemicals that are intentionally added to products (Phase 3 text, page 2), it may be appropriate to remove from the draft reporting list substances such as 1,4-dioxane (process byproduct of ethoxylation).

Reporting Trigger Levels

Health-based Categorization

Because the Ecology draft reporting list contains many chemicals that are included based on their potential systemic effects (i.e., non-CMR chemicals), a categorization scheme separate from existing lists of CMR substances is needed. Thus, in order to develop a health-based system for assigning reporting trigger levels to the substances on the revised draft reporting list, it is appropriate first to refer to USEPA's Regional Screening Level (RSL) table, which is used by USEPA and others for preliminary evaluation of contaminated sites. The RSL table contains consensus toxicological guidance values for more than seven hundred chemicals. As detailed in our previous submittal, inhalation exposure and potential carcinogenicity are highly uncertain aspects of children's interaction with toys and other products. The RSL table can be refined to focus on potential

adverse systemic (noncarcinogenic) effects from "ingestion only" by looking at those chemicals that have only a promulgated oral reference dose (RfD). This refined list contains 338 chemicals. In order to establish a baseline for putting the relative toxicity of the substances on the draft reporting list into perspective, the refined RSL list can be broken down into the following four categories:

- Category 1 represents the approximately 5% (5.62%) of chemicals that have the lowest oral toxicity, based on having the highest (least restrictive) oral RfD. In this instance, this represents the 19 of 338 chemicals that have an oral RfD greater than 5.0E-01 mg/kg•day (0.5 mg/kg•day);
- Category 2 is the 30% of chemicals on the refined RSL table that have oral RfD values ≥3.0E-02 mg/kg•day and ≤5.0E-01 mg/kg•day (0.03 mg/kg•day to 0.5 mg/kg•day);
- Category 3 is represented by the 33% whose oral RfD is >3.0E-03 mg/kg•day and <3.0E-02 mg/kg•day (0.003 mg/kg•day to 0.03 mg/kg•day); and,
- Category 4 is the 32% with oral RfD values ≤3.0E-03 mg/kg•day (0.003 mg/kg•day).

Using those four principal categories, and in a manner analogous to the process envisioned by the EU's REACH guidelines, where trigger levels for the majority of chemicals are set at a default total chemical level of 0.1% (1,000 ppm) by weight of total product, we propose that substances within the oral RfD range defined as Category 3 would be assigned a reporting trigger level of 0.1%, or as noted otherwise. The 1,000 ppm guidance level also is suggested as the more restrictive of two possible thresholds which trigger reporting requirements under Section 313 of the Superfund Amendments and Reauthorization Act (SARA 313). Stated differently, the product would be 99.9% free of the substance of interest (ratio of 0.001 to 0.999).

The approximately 5% of chemicals with the lowest oral toxicity (Category 1) would be assigned a trigger level of 10% (100,000 ppm). Categories 2 and 4 would be assigned reporting trigger levels of 1% (10,000 ppm) and 0.01% (100 ppm), respectively. Those chemicals that do not have an oral RfD are proposed for inclusion in Category 3 (trigger level of 0.1%). Table 2 presents the refined draft reporting list in order of ascending potential toxicity, based on oral RfD values, along with the possible trigger levels according to this simplified, toxicity-based approach.

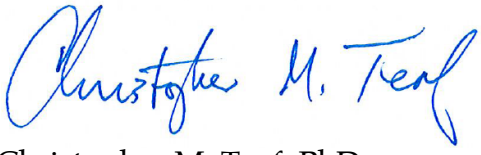
Final Thoughts

In addition to the health-based, RfD-based system recommended above, it may be advisable to institute a first step "CMR phase" in which any consensus CMR chemicals are assigned trigger levels based on their CMR category (e.g., 0.1% for CMR 1 and CMR 2; 1% for CMR 3). This CMR phase would take priority over the RfD-based determination for those substances, and would bring the process more in line with the EU system.

The trigger levels in this categorization scheme are intended for use as the most restrictive upper limits for chemicals in finished products or in mixtures/preparations, whether in solid, liquid or gel form. It is acknowledged that such a distinction is important, and the proposed trigger levels may be more restrictive than necessary depending on the exposure matrix. Stated differently, from a health-based perspective, lower concentrations than the proposed reporting trigger levels are not deemed necessary, but the trigger level may be adjusted upward depending on the matrix in which the substance occurs.

Please call Doug Covert or me at (850) 681-6894 when you have had an opportunity to review this information, so we can answer any questions or provide clarification as appropriate.

Sincerely,



Christopher M. Teaf, PhD
President & Director of Toxicology

Table 1

Refined Draft Reporting List for CPSA Reporting Rule

Substance	CAS #
1,1,2,2-Tetrachloroethane	79-34-5
1,4-Dioxane	123-91-1
2-Aminotoluene	95-53-4
2-Ethylhexanoic Acid	149-57-5
2-Methoxyethanol	109-86-4
2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether; BDE-209	1163-19-5
2,4-Diaminotoluene	95-80-7
3,3´-Dimethylbenzidine and Dyes Metabolized to 3,3´-Dimethylbenzidine	119-93-7
4-octyl-Phenol	1806-26-4
Acetaldehyde	75-07-0
Acrylonitrile	107-13-1
Aniline	62-53-3
Arsenic & Arsenic compounds	7440-38-2
Benzene	71-43-2
Beryllium & Beryllium compounds	7440-41-7
Bisphenol A	80-05-7
C.I. Solvent Yellow 14	842-07-9
Carbon disulfide	75-15-0
Cobalt & Cobalt compounds	7440-48-4
Di-n-Hexyl Phthalate	84-75-3
Ethylbenzene	100-41-4
Ethylene glycol	107-21-1
Ethylene glycol monoethyl ether	110-80-5
Formaldehyde	50-00-0
Mercury & mercury compounds	7439-97-6
Methyl ethyl ketone	78-93-3
Methylene chloride	75-09-2
n-Butanol	71-36-3
N-Methylpyrrolidone	872-50-4
N-Nitrosodimethylamine	62-75-9
N-Nitrosodiphenylamine	86-30-6
Nonylphenol	25154-52-3
para-Chloroaniline	106-47-8
Perchloroethylene	127-18-4
Perfluorooctanyl sulphonic acid and its salts; PFOS	1763-23-1
Phenol	108-95-2
Styrene	100-42-5
Toluene	108-88-3
Tris(2-chloroethyl) phosphate	115-96-8
Vinyl chloride	75-01-4

Table 2

Proposed Reporting Trigger Levels for Refined Draft Reporting List for CPSA Reporting Rule

Substance	CAS #	Oral RfD (mg/kg•day)	Proposed Trigger Level (ppm)	Proposed Trigger Level (%)
Ethylene glycol	107-21-1	2.0E+00	100,000	10%
Methyl ethyl ketone	78-93-3	6.0E-01	100,000	10%
Ethylene glycol monoethyl ether	110-80-5	4.0E-01	10,000	1.0%
Phenol	108-95-2	3.0E-01	10,000	1.0%
Formaldehyde	50-00-0	2.0E-01	10,000	1.0%
Styrene	100-42-5	2.0E-01	10,000	1.0%
1,4-Dioxane	123-91-1	1.0E-01	10,000	1.0%
Carbon disulfide	75-15-0	1.0E-01	10,000	1.0%
Ethylbenzene	100-41-4	1.0E-01	10,000	1.0%
n-Butanol	71-36-3	1.0E-01	10,000	1.0%
Toluene	108-88-3	8.0E-02	10,000	1.0%
Methylene chloride	75-09-2	6.0E-02	10,000	1.0%
Bisphenol A	80-05-7	5.0E-02	10,000	1.0%
Acrylonitrile	107-13-1	4.0E-02	10,000	1.0%
Aniline *	62-53-3	7.0E-03	10,000	1.0%
2-Ethylhexanoic Acid *	149-57-5	**NF**	10,000	1.0%
Acetaldehyde *	75-07-0	**NF**	10,000	1.0%
Nonylphenol *	25154-52-3	**NF**	10,000	1.0%
2-Aminotoluene	95-53-4	**NF**	1,000	0.1%
2,4-Diaminotoluene	95-80-7	**NF**	1,000	0.1%
C.I. Solvent Yellow 14	842-07-9	**NF**	1,000	0.1%
Di-n-Hexyl Phthalate	84-75-3	**NF**	1,000	0.1%
N-Methylpyrrolidone	872-50-4	**NF**	1,000	0.1%
N-Nitrosodiphenylamine	86-30-6	**NF**	1,000	0.1%
perfluorooctanyl sulphonic acid and its salts; PFOS	1763-23-1	**NF**	1,000	0.1%
Phenol, 4-octyl-	1806-26-4	**NF**	1,000	0.1%
Perchloroethylene	127-18-4	1.0E-02	1,000	0.1%
Cobalt & Cobalt compounds	7440-48-4	9.0E-03	1,000	0.1%
2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether; BDE-209	1163-19-5	7.0E-03	1,000	0.1%
Tris(2-chloroethyl) phosphate	115-96-8	7.0E-03	1,000	0.1%
1,1,2,2-Tetrachloroethane	79-34-5	4.0E-03	1,000	0.1%
para-Chloroaniline	106-47-8	4.0E-03	1,000	0.1%
3,3´-Dimethylbenzidine and Dyes Metabolized to 3,3´-Dimethylbenzidine	119-93-7	**NF**	100	0.01%
Benzene	71-43-2	4.0E-03	100	0.01%
2-Methoxyethanol	109-86-4	3.0E-03	100	0.01%
Vinyl chloride	75-01-4	3.0E-03	100	0.01%
Beryllium & Beryllium compounds	7440-41-7	2.0E-03	100	0.01%
Arsenic & Arsenic compounds	7440-38-2	3.0E-04	100	0.01%
Mercury & mercury compounds	7439-97-6	1.6E-04	100	0.01%
N-Nitrosodimethylamine	62-75-9	8.0E-06	100	0.01%

NF No oral RfD found in RSL database

Oral RfD >5.0E-01 (5% of 338 RSL Chemicals that have only an oral RfD) **Cat 1 (10%; 100,000 ppm)**

5.0E-01 ≥ Oral RfD ≥ 3.0E-02 **Cat 2 (1%; 10,000 ppm)**

* Noted substances were added to Category 2 for consistency with REACH CMR 3 designation and content limit.

3.0E-02 > Oral RfD > 3.0E-03 OR no oral RfD found in RSL **Cat 3 (0.1%; 1,000 ppm)**

Oral RfD ≤ 3.0E-03 **Cat 4 (0.01%; 100 ppm)**

3,3'-Dimethylbenzidine, as well as known human carcinogen benzene were added to Category 4.